

**IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF NORTH CAROLINA
ASHEVILLE DIVISION
1:12cv312**

EUGENE ALLEN BRADLEY,)	
)	
Plaintiff,)	
)	
v.)	MEMORANDUM AND RECOMMENDATION
)	
BAXTER HEALTHCARE)	
CORPORATION and PHARMACIA &)	
UPJOHN COMPANY LLC,)	
)	
Defendants.)	
)	

Pending before the Court is the Motion to Dismiss [# 9] filed by Defendant Pharmacia & Upjohn Company LLC (“Pharmacia” or “Defendant”). Plaintiff brought this action against Defendant asserting state law claims for negligence, breach of warranty, and products liability arising out of the alleged negligent design and manufacture of Gelfoam. Defendant moves to dismiss all the claims asserted against it because the claims are preempted by the Medical Device Amendments to the Food, Drug, and Cosmetic Act. The Court **RECOMMENDS** that the District Court **GRANT** the motion [# 9].

I. Background

In 2007, Plaintiff underwent a lumbar fusion surgery to address lower back

pain. (Pl.’s Compl. ¶¶ 7, 13.) The doctor performing the surgery used the product Gelfoam during the surgical procedure. (Id. ¶ 14.) Gelfoam is manufactured by Defendant. (Id. ¶¶ 23, 49.)

Plaintiff contends that Gelfoam did not perform as intended, was defective, and caused further spinal canal narrowing and stenosis. (Id. ¶¶ 16-17, 21, 56.) In addition, Plaintiff contends that Defendant was negligent in the design of Gelfoam. (Id. ¶ 59.) Subsequently, Plaintiff had further surgery to correct the spinal condition caused by the defective Gelfoam. (Id. ¶¶ 19-21.) Plaintiff then brought this action alleging state law claims for negligence, breach of warranty, and products liability against Defendant. Defendant moves to dismiss the claims asserted against it in the Complaint. Defendant’s Motion to Dismiss is now properly before this Court for a Memorandum and Recommendation to the District Court.

II. Legal Standard

The central issue for resolving a Rule 12(b)(6) motion is whether the claims state a plausible claim for relief. See Francis v. Giacomelli, 588 F.3d 186, 189 (4th Cir. 2009). In considering Defendant’s motion, the Court accepts the allegations in the Complaint as true and construes them in the light most favorable to the Plaintiff. Nemet Chevrolet, Ltd. v. Consumeraffairs.com, Inc., 591 F.3d 250, 253

(4th Cir. 2009); Giacomelli, 588 F.3d at 190-92. Although the Court accepts well-pled facts as true, it is not required to accept “legal conclusions, elements of a cause of action, and bare assertions devoid of further factual enhancement” Consumeraffairs.com, 591 F.3d at 255; see also Giacomelli, 588 F.3d at 189.

The claims need not contain “detailed factual allegations,” but must contain sufficient factual allegations to suggest the required elements of a cause of action. Bell Atlantic Corp. v. Twombly, 550 U.S. 544, 555, 127 S. Ct. 1955, 1964-65 (2007); see also Consumeraffairs.com, 591 F.3d at 256. “[A] formulaic recitation of the elements of a cause of action will not do.” Twombly, 550 U.S. at 555, 127 S. Ct. at 1965. Nor will mere labels and legal conclusions suffice. Id. Rule 8 of the Federal Rules of Civil Procedure “demands more than an unadorned, the defendant-unlawfully-harmed-me accusation.” Ashcroft v. Iqbal, 556 U.S. 662, 678, 129 S. Ct. 1937, 1949 (2009).

The Complaint is required to contain “enough facts to state a claim to relief that is plausible on its face.” Twombly, 550 U.S. at 570, 127 S. Ct. at 1974; see also Consumeraffairs.com, 591 F.3d at 255. “A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged.” Iqbal, 556 U.S. at 678, 129 S. Ct. at 1949; see also Consumeraffairs.com, 591 F.3d

at 255. The mere possibility that a defendant acted unlawfully is not sufficient for a claim to survive a motion to dismiss. Consumeraffairs.com, 591 F.3d at 256; Giacomelli, 588 F.3d at 193. Ultimately, the well-pled factual allegations must move a plaintiff's claim from possible to plausible. Twombly, 550 U.S. at 570, 127 S. Ct. at 1974; Consumeraffairs.com, 591 F.3d at 256.

III. Analysis

A. Plaintiff's Claims are Preempted

Congress enacted the Medical Device Amendments of 1976 ("MDA") in order to impose detailed federal oversight over medical devices. Riegel v. Medtronic, Inc., 552 U.S. 312, 316, 128 S. Ct. 999, 1003 (2008); Walker v. Medtronic, Inc., 670 F.3d 569, 572 (4th Cir. 2012). As a means of creating uniform federal regulations, the MDA included an express preemption provision, which provides in relevant part:

[N]o State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement--

(1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and

(2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.

21 U.S.C. § 360k(a).

In addition, the MDA established three classes of medical devices. Walker, 670 F.3d at 572. Class III devices received the highest level of federal oversight. Id. Because of the risk related to the use of Class III devices, these devices must receive pre-market approval from the FDA. Reigel, 552 U.S. at 317, 128 S. Ct. 1003-04; Walker, 670 F.3d at 573. “Once a device has received premarket approval, the MDA forbids the manufacturer to make, without FDA permission, changes in design specifications, manufacturing processes, labeling, or any other attribute that would affect safety or effectiveness.” Reigel, 552 U.S. at 319, 128 S. Ct. at 1005.

In Reigel, the United States Supreme Court considered whether common law claims such as strict liability, breach of implied warranty, and negligent design, labeling and manufacturing were preempted by the MDA where such claims were based on the failure of a Class III device. 552 U.S. at 320-21, 128 S. Ct. 1005-06. “[T]he Supreme Court held that the terms of a Class III device’s premarket approval constitute federal requirements and that a common law tort claim premised on different or additional requirements is preempted by the MDA.” Walker, 670 F.3d at 377. The Supreme Court held that the specific claims asserted by the plaintiff were preempted. Reigel, 552 U.S. at 330, 128 S. Ct. at 1011. The Supreme Court, however, recognized one situation where a plaintiff’s common law

claims could survive preemption: where the state imposed parallel, rather than additional, duties to the federal requirements. Id.; Walker, 670 F.3d at 577. “This situation occurs when claims are ‘premised on a violation of FDA regulations.’” Walker, 670 F.3d at 577 (quoting Reigel, 552 U.S. at 330, 128 S. Ct. 999).

Defendant’s Gelfoam is a Class III medical device that went through the FDA’s premarket approval process pursuant to the MDA. (Ex. A to Def.’s Mot. Dismiss.) As such, states cannot impose additional requirements over and above those set by the FDA for the device. See Reigel, 552 U.S. at 321-25, 128 S. Ct. at 1006-09. Here, Plaintiff is attempting to impose restrictions on Defendant over and beyond the specifications imposed by the FDA as part of the premarket approval by asserting state law claims for negligence, products liability, and breach of warranty. As numerous courts have held, such claims are preempted by the MDA. See id.; Walker, 670 F.3d at 580-81 (collecting cases).

Moreover, Plaintiff may not rely on the exception to preemption set forth by the Supreme Court in Reigel to escape dismissal of the claims asserted against Defendant. Although a plaintiff may maintain a suit based on violations of FDA regulations, the Complaint fails to set forth a single factual allegation supporting such a claim. The conclusory allegations in the Complaint that Defendant failed to comply with 21 U.S.C. § 351 and the FDA’s Good Manufacturing Practice

Requirements are insufficient to state a claim in federal court. See Twombly, 550 U.S. at 555, 127 S. Ct. at 1965; see also Smith v. St. Jude Med. Cardiac Rhythm Mgmt. Div., Civil Case No. CCB-12-1746, 2013 WL 1104427, at *3-4 (D. Md. Mar. 13, 2013) (holding that conclusory allegations that the defendant failed to comply with FDA specifications were insufficient to avoid preemption under the MDA); Ali v. Allergan USA, Inc., No. 1:12-CV-115 (GBL/TRJ), 2012 WL 3692396, at *6 (E.D. Va. Aug. 23, 2012) (“conclusory allegations that the defendant violated FDA regulations in the manufacture, labeling, or marketing of the pre-market approved medical device are insufficient to state a parallel state-law claim and thereby avoid preemption under § 360k(a)’’); Viserta v. St. Jude Med., Inc., C.A. No. 8:11-cv-00505-JMC, 2012 WL 667814, at *3 (D.S.C. Feb. 29, 2012) (collecting cases).

B. Plaintiff’s Request for Leave to Amend is Improper

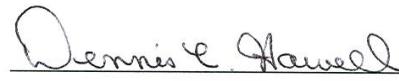
In the response to Defendant’s Motion to Dismiss, Plaintiff also asserts that if this Court finds that Plaintiff has failed to state a claim, that the Court should grant Plaintiff leave to amend the Complaint. The Local Rules of this Court, however, prohibit the inclusion of a motion in a response brief. LCvR 7.1(C)(2). The Local Rule is plain and clear: “Motions shall not be included in response briefs. Each motion should be set form as a separately filed pleading.” Id.

Because Plaintiff has not complied with the Court's Local Rules, there is no motion for the Court to rule upon, and the Court will not grant Plaintiff leave to amend.

IV. Conclusion

The Court **RECOMMENDS** that the District Court **GRANT** the Motion to Dismiss [# 9] and **DISMISS** all the claims asserted against Defendant Pharmacia & Upjohn Company LLC.

Signed: October 18, 2013



Dennis L. Howell
United States Magistrate Judge 

Time for Objections

The parties are hereby advised that, pursuant to 28, United States Code, Section 636(b)(1)(C), and Rule 72, Federal Rules of Civil Procedure, written objections to the findings of fact, conclusions of law, and recommendation contained herein must be filed within **fourteen (14)** days of service of same.

Responses to the objections must be filed within fourteen (14) days of service of the objections. Failure to file objections to this Memorandum and Recommendation with the district court will preclude the parties from raising such objections on appeal. Thomas v. Arn, 474 U.S. 140 (1985), reh'g denied, 474 U.S. 1111 (1986); United States v. Schronce, 727 F.2d 91 (4th Cir.), cert. denied, 467 U.S. 1208 (1984).